510(K) SUMMARY

K043245

APR 2 9 2005

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: **EPS Bio Technology Corp.**

Address: 2F, No.49-2, Lane 2, Guang Fu Rd., Sec. 2, Hsinchu City , Taiwan, R.O.C.

Phone: 886-3-5752522

Fax: 886-3-5752552

Contact: Mr. Y.C. Lei, General Manager

2.0 Device Name: A. Easy Pain Supreme Self-Monitoring Blood Glucose System

3.0 Classification: Class II

4.0 Predicate Device: The predicate device is the Precision® QID Blood Glucose Testing System (K 971812) marketed by Medisense Inc.

5.0 Device Description: The Easy Pain Supreme Self-Monitoring Blood Glucose System consists of the Easy Pain Supreme meter, Easy Pain Supreme Glucose Test Strips, Auto-Lancet Device, Check Strip, Code Card, and Control Solution.

6.0 Indication for Use: The Easy Pain Supreme Self-Monitoring Blood Glucose System is used by individuals with diabetes. It is for the quantitative measurement of glucose levels in fresh capillary whole blood, as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings.

Special condition for use statement(s) :
Provides plasma equivalent results.

Special instrument Requirements : N/A

7.0 Comparison with predicate :

Similarities		
Item	Device	Predicated
	Easy Pain Supreme	**Precision QID**
Detection method	Amperometry : current is generated by oxidation of reduced mediator.	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Electrode	Carbon electrode	Carbon electrode

Differences		
Item	Device	Predicated
	Easy Pain Supreme	**Precision QID**
Test range	**40-600 mg/dL**	20-600 mg/dL
Hematocrit Range	30-55%	20-70%
Test Time	25 seconds	20 seconds
Sample Volume	≧2.0uL	≧3.5uL
Operating Range **Temperature** **Humidity range**	 10-40℃ R.H.≦90%	 18-30℃ R.H. : 10% to 90%
Open use time	3 months	3 months
Coding	Code Card	Calibrator
Memory	100 blood glucose tests with	NA
Capability	Date and time	
Power	1.5V (AAA)*2 batteries	Non-replaceable cell 3.0 V/DC
Battery life	Approximately 1,000 glucose tests	Approximately 4,000 glucose tests
Size : L x W x H (cm)	7.5 x 5.4 x 1.9	9.7 x 4.80 x 1.45
Weight	50g (without batteries)	39.35gram

8.0 Test Principle

The Easy Pain Supreme Self-Monitoring Blood Glucose System employs a disposable dry reagent strip technology, based on the glucose oxidase method for glucose determination. Each test strip features an electrode containing the enzyme glucose oxidase (Aspergillus niger). A blood sample is applied to the blood collection area at the tip of the strip and is automatically drawn into the reaction zone, where the glucose oxidase catalyzes the oxidation of glucose to produce gluconic acid. During the reaction, a mediator transfers electrons to the electrode surface and generates a current. The amount of the current is proportional to the amount of glucose present in the blood sample the glucose concentration is measured by the Easy Pain Supreme Glucose Meter and displayed on the screen after 25 seconds.

9.0 Performance Characteristics

1. Analytical performance :

Precision / Reproducibility :

Testing was conducted by taking 4 mL of blood that was treated with Heparin through a vacuum tube. Glucose was added to the 4 mL of blood to generate 5 different levels of glucose concentration for the test. Each of the samples was measured 5 times. Below are the glucose concentration ranges for each level that were measured. (See Table I for Summary of Test Results)

Level	Glucose Concentration Range
1	***40-50 mg/dL***
2	*51-110 mg/dL*
3	*111-150 mg/dL*
4	*151-250 mg/dL*
5	*251-400 mg/dL*

Three control solutions of Low, Normal and High were prepared. Each of the controls was measured twice a day, once in the morning and once in the afternoon for a month. (Table I (below) shows a summary of the Within-Run Precision and the Day-to-Day Precision Tests.)

Table I : Summary of Test Results

Within-Run Precision

Control Samples	*No. Of Assay*	*Mean (mg/dL)*	*SD(mg/dL)*	*CV(%)*
Level 1	*200*	*43*	***2.4***	*4.3*
Level 2	*200*	*95*	***5.3***	*3.5*
Level 3	*200*	*144*	***8.0***	*3.3*
Level 4	*200*	*246*	***13.7***	*3.1*
Level 5	*200*	*398*	***22.1***	*3.3*

Day-to-Day Precision

Control Samples	*No. Of Assay*	*Mean (mg/dL)*	*SD(mg/dL)*	*CV(%)*
Low	*400*	*56*	*3.10*	*5.6*
Normal	*400*	*129*	*4.49*	*3.5*
High	*400*	*388*	*10.21*	*2.6*

9.0 Performance Characteristics(Cont.)

a. **Linearity / assay reportable range :**

A blood sample of 25 mL was taken, treated with Heparin vacuum tube, to be set for a day, Testing was performed using whole blood supplemented with β-D-glucose to provide samples at seven different blood glucose levels. A total of 210 tests were preformed using 5 meters among the seven glucose ranges per each strip lot. The glucose linearity dilution study demonstrated the following regression :

mmol/L	***mg/dL***
2.2- 2.8	**40- 50**
2.8-4.3	**51-80**
4.4-6.7	**81-120**
6.7-11.1	**121-200**
11.2-16.6	**201-300**
16.7-22.2	**301-400**
22.3-33.3	400-600

Y=0.9589x + 6.1617
R2=0.9958 ; Syx=10.14 ; N=630

b. *Traceability (controls, calibrators, or method) :*

CAS# (Chemical Abstract Service)
MDL# (MDL, inc. formerly Molecular Design Laboratories)
Glucose #492615 SigmaUltra MFCD00063989
Traceability referenced to NBS, NIST Standards

c. *Detection limit :*

40-600 mg/dL
2.2-33.3 mmol/L

d. *Analytical Specifiecity :*

Interference testing was conducted to determine the effect of select endogenous and exogenous substances. A series of test samples, systematically varying in the concentration of the interferents, was prepared by making quantitative, volumetric mixtures of two pools : one at the highest concentration to be tested and the other at the lowest. The substances and concentrations of the interferents are recommended at NCCLS EP7-P.

e. *Assay cut-off :* N/A

2. Comparison studies :

a. ***Method comparison with predicate device :***

The accuracy of the Easy Pain Supreme Self-Monitoring Blood Glucose System was assessed by comparing blood glucose results obtained by patients with those obtained using the YSI 2300 Analyzer. The results below were obtained by 202 subjects with diabetes at three independent clinics. The regression statistics are derived from a plot of the EPS capillary data versus YSI plasma data.

The Linear regression of the 202 diabetic patients – YSI 2300 vs. easy Pain Supreme System presented the following regression :

Slope=	*0.967*
y-intercept	11.98 mg/dL
Correlation coefficient(r)	0.972
No. of samples	202
Range tested	33-514 mg/dL

b. Matrix comparison : N/A

3. Clinical studies :

a. Clinical sensitivity : N/A

b. *Clinical specificity :* N/A

c. *Other clinical supportive data (when a and b are not applicable) :*

See Attachment 12

4. Clinical cut-off : **N/A**

5. Expected Values/Reference range :

Expected blood glucose levels for people without diabetes :

Time	Range (mg/dL)	Range (mmol/L)
Before Breakfast :	70 – 105	3.9 – 5.8
Before Lunch or Dinner :	70 – 110	3.9 – 6.1
1 hour after meals :	Less than 160	Less than 8.9
2 hour after meals :	Less than 120	Less than 6.7
Between 2 and 4 AM	Greater than 70	Greater than 3.9

Where the above Expected Values is referenced from Joslin Diabetes Manual

8. Conclusions:

The **Easy Pain Supreme Self-Monitoring Blood Glucose System** have the same intended use and similar technological characteristics as Precision® QID Blood Glucose Testing System (K 971812) marketed by Medisense Inc.. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **Easy Pain Supreme Self-Monitoring Blood Glucose System** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 9 2005

EPS Bio Technology Corp.
c/o Ms. Jennifer Reich
US Agent
Harvest Consulting Corporation
3892 South America West Trail
Flagstaff, AZ 86001

Re: k043245
Trade/Device Name: Easy Pain Supreme Self-Monitoring Blood Glucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: March 18, 2005
Received: March 25, 2005

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043245

Device Name: **Easy Pain Supreme Self-Monitoring Blood Glucose System**

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Prescription Use _____ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K043245